EXHIBIT M

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider

DEFENDANTS' FACT SHEET

Commented [JS1]: The Pharmacy/Retailer Defendants adopt and incorporate by reference all defense edits to the DFS proposed by the non-pharmacy defendants on 10/23.

In accordance with Case Management Order No. __, within 90 days of being served with a substantially completed Plaintiff Fact Sheet ("PFS") verified with the required declaration, the [Defendants served with the PFS – (may be subject to revision based on resolution of "macro" discovery issues)] must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on Plaintiffs' Co-Lead Counsel.[1] The Defendants will not be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS, which must provide all of the information requested in Section I of the PFS, including copies of prescription and/or pharmacy records demonstrating use of a Valsartan-containing drug, and, for personal injury plaintiffs, including medical records and/or a certification under oath demonstrating that he or she has been diagnosed with cancer by a licensed physician, and a signed HIPAA authorization.

Each served Defendant must complete the section(s) of this DFS that correspond with that Defendant's role(s) in the supply chain for the Affected Drugs (defined below). Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant, or, if applicable, the responding Defendant may produce or cite to produced documents or business records by bates number in accordance with Federal Rule of Civil Procedure 33(d).

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

"AFFECTED DRUGS": The Valsartan-containing drugs purchased by the Plaintiff submitting the PFS (the "Responding Plaintiff")[2],~~s~~ ~~that~~ which have been identified with specificity in Sections

[1] Defendants who are subject to the Protocol for Dismissals of Certain Defendants Without Prejudice approved in Case Management Order No. 15 (ECF 247) are excluded from responding to the DFS.

[2] Reference herein to "Plaintiff" or "Responding Plaintiff" is inclusive of any Plaintiff serving in a representative capacity for an individual who was prescribed valsartan and upon which the underlying claim is based.

I.B. and I.C of the PFS and confirmed through Responding Plaintiff's pharmacy records produced pursuant to the PFS.

"DOCUMENTS": "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

"YOU," "YOUR," or "YOURS": Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. API MANUFACTURERS

A. Identify whether you manufactured the Valsartan API used in any Affected Drug(s) and, if so, which Affected Drug(s).

B. For each Affected Drug listed in response to Question II.A, provide the date the API was manufactured and the place of manufacture (by facility, city, state, and country).

C. Identify the entity or entities to which you sold or distributed each Affected Drug identified in response to Question II.A and the date on which each sale or distribution occurred.

D. For each Affected Drug identified in response to Question II.A, identify (1) any test results from chromatography testing that you conducted on that batch or lot of API, and (2) any test result that you received from a third party for chromatography done on that lot or batch of API.

E. State whether you supplied each test result identified in response to Question II.F to the FDA, or to any other entity named as a Defendant in the applicable Short Form Complaint, and, if so, provide the recipient of the test result and the date of communication.

F. Provide the date(s) on which you sent any recall notice that applied to any Affected Drug(s) to any Defendants identified in the applicable Short Form Complaint and attach the recall notice(s).

G. Have Plaintiff's records identified that any Affected Drugs incorporating the Valsartan API that you sold, distributed, labeled, or manufactured in whole or in part were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA impurities, or for allegedly or possibly containing NDMA or NDEA?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any chromatography testing you conducted on the returned drugs after they were returned to your possession.

If no, but you have knowledge of the location of the drugs, provide the location:

H. Have you contacted Plaintiff directly at any time?

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

III. FINISHED DOSE MANUFACTURERS

A. Identify whether you are the finished dose manufacturer for any Affected Drug(s) and, if so, which Affected Drug(s).

B. For each Affected Drug identified in response to Question III.A, provide the API manufacturer.

C. For each Affected Drug identified in response to Question III.A, identify the entity or entities to which you sold or distributed each Affected Drug and the date on which each sale or distribution occurred.

D. For each Affected Drug identified in response to Question III.A, identify (1) any chromatography testing that you conducted on the Affected Drug, or (2) any test result that you received from a third party for chromatography done on the Affected Drug.

E. State whether you supplied each test result identified in response to Question III.D to the FDA, or to any other entity named as a Defendant in the applicable Short

Form Complaint and, if so, provide the recipient of the test result and the date of communication.

F. Provide the date(s) on which you sent any recall notice that applied to any Affected Drug(s) to any Defendants identified in the applicable Short Form Complaint and attach the recall notice(s) or cite to them by bates number.

G. Have Plaintiff's records identified that any Affected Drugs sold, distributed, labeled, or manufactured in whole or in part by you were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA impurities, or for allegedly or possibly containing NDMA or NDEA?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any chromatography testing you conducted on the returned drugs after they were returned to your possession.

If no, but you have knowledge of the location of the drugs, provide the location:

H. Have you contacted Plaintiff directly at any time?

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

I. Please produce a copy of any adverse event report, including any MedWatch form, that relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

IV. REPACKAGERS, LABELERS, WHOLESALERS, and DISTRIBUTORS

A. Identify whether you are the repackager, labeler, wholesaler, and/or distributor for any Affected Drug(s) and, if so, which Affected Drug(s).

B. For each Affected Drug listed in response to Question IV.A, provide the date of purchase and the entity from which the Affected Drug was purchased.

C. For each Affected Drug listed in response to Question IV.A, identify the entity or entities to which you sold or distributed the Affected Drug and the date on which each sale or distribution occurred.

D. For each Affected Drug identified in response to Question IV.A, identify (1) any test results from chromatography testing that you conducted on the Affected Drug.

E. State whether you supplied each test result identified in response to Question IV.D to the FDA, or to any other entity named as a Defendant in the applicable Short Form Complaint and, if so, provide the recipient of the test result and the date of communication.

F. Provide the date(s) on which you sent any type of communication to Plaintiff relating to valsartan-containing drugs and/or a recall of any valsartan-containing drugs.

G. Have Plaintiff's records identified that any Affected Drugs sold, wholesaled, distributed, labeled, or manufactured in whole or in part by you were ever returned to your possession as a result of a recall letter related to potential NDMA or NDEA impurities, or for allegedly or possibly containing NDMA or NDEA?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any chromatography testing you conducted on the returned Affected Drugs after they were returned to your possession.

H. Please produce a copy of any adverse event report, including any MedWatch form that relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

V. PHARMACIES[3]

A. ~~Identify whether you are the pharmacy that dispensed any Affected Drug(s) and, if so, which Affected Drug(s), and identify which were contaminated with any~~

[3] This class of defendants is referenced as "pharmacies" only for convenience and consistency with the characterizations in the pleadings, but the defendants do not concede that each named defendant is in fact a "pharmacy."

~~nitrosamine or other carcinogenic substance.~~ For each alleged Affected Drug identified in Section I.B. and I.C. of the PFS, confirm that you dispensed the alleged Affected Drug to the Responding Plaintiff, and provide dispensing information as follows. Dispensing records reflecting the information in Section V.A. may be submitted in lieu of written response.

1. Name and address of Pharmacy(ies) dispensing the alleged Affected Drug, including any store identifiers (e.g. Pharmacy No. 123);

2. Date(s) on which the alleged Affected Drug was dispensed to Plaintiff;

3. National Drug Code ("NDC") associated with all dispensation of the alleged Affected Drug;

4. Quantity of alleged Affected Drug dispensed to Responding Plaintiff on each dispensation date;

4. Amounts paid by Responding Plaintiff for the alleged Affected Drug on each dispensation date;

5. Amounts paid, if known, by anyone other than Responding Plaintiff for the alleged Affected Drug on each dispensation date.

Commented [JS2]: The Pharmacy/Retail Defendants have conferred with their respective clients and state that, for the vast majority of the Pharmacy/Retail Defendants, lot and batch information cannot be determined at the point of sale, as that information is not tracked. The Pharmacy/Retail Defendants can meet and confer to discuss the information that can be provided, but it is not possible to link a specific batch/lot to a particular Plaintiff/patient; this section will need to be revised to reflect this. See our proposed edits.

~~A. For each Affected Drug listed in response to Question V.A, provide the date of purchase, the entity from whom the Affected Drug was purchased, the purchase price including amounts paid by the consumer and any insurance carrier or other payor, and the location of purchase.~~

~~B. For each Affected Drug identified in response to Question V.A, identify any testing done on that lot/batch that you were provided or conducted (1) to identify any impurity or artifact, (2) to identify nitrosamines, (3) that identified any impurity or artifact, including but not limited to a nitrosamine, and (4) the full result of that testing.~~

~~C. State whether you supplied each test result identified in response to Question V.C to the FDA, or to any other entity or person, and if so identify the test result, and provide the recipient, date, and content.~~

Commented [JS3]: The Pharmacy/Retail Defendants have conferred with their respective clients and believe that no testing is done or ordered to identify impurities generally or nitrosamines specifically at the pharmacy level for these named Defendants.

~~D. Have you communicated directly with Plaintiff at any time?~~

~~Yes____ No____~~

~~If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.~~

~~E.~~B. Did you send any communication to Responding Plaintiff regarding any recall of valsartan and/or any potential valsartan impurities? If yes, ~~P~~provide the date(s) on which you sent ~~any type of~~such communication to Responding Plaintiff ~~or any other person or entity relating to actual or potential contamination of valsartan~~

~~containing drugs and/or a recall of any valsartan-containing drugs~~. If available, provide a copy of the communication(s), letter(s), or template letter(s) sent to Responding Plaintiff relating to any recall of valsartan and/or any potential valsartan impurities.

~~F. Identify all Affected Drugs that you or any entity has recalled, or identified as contaminated or potentially contaminated.~~

~~G.~~C. ~~Were~~ Was any valsartan ~~Affected Drugs~~ sold by you to Responding Plaintiff ever returned to your possession as a result of a recall letter, or finding or suspicion of contamination? The following information must be provided to the extent it exists and is reasonably accessible.

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any nitrosamine-related testing done on the returned drugs.

If no, but you have knowledge of the location of the drugs, provide the location:

Commented [JS4]: These are preliminary comments. Counsel for the various Pharmacy/Retail Defendants are conferring with their respective clients to determine the information that these entities have in their possession or control regarding the reverse distribution process for valsartan potentially implicated in a recall. Therefore, we request to defer this issue until this information can be confirmed.

~~H. Please produce a copy of any adverse event report, including but any MedWatch form which relates to the Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.~~

~~I. If you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):~~

~~1. Identify the Alternate Cause with specificity.~~

~~2. Set for the date(s) and mechanism of alternate causation.~~

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date:_____ _____
Signature

Name:_____